

"The need for choline and inositol in human nutrition has not been established," as required by regulations.

The libel alleged also that the article was misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6013.

DISPOSITION: 7-8-59. Consent—claimed by Dr. Reeves' Products, Inc., and relabeled.

26740. Rybutol gelucaps. (F.D.C. No. 42560. S. Nos. 24-427/8 P.)

QUANTITY: 24 btl. and 12 btl., each containing 250 capsules, at Los Angeles, Calif.

SHIPPED: Between 2-3-58 and 6-13-58, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Examination showed that the 24-btl. lot contained approximately 74 percent of the declared amount of vitamin C, and the 12-btl. lot contained approximately 50 percent of the declared amount of vitamin B₁₂.

LIBELED: 12-31-58, S. Dist. Calif.

CHARGE: 402(b) (1)—while held for sale, the valuable constituents, vitamin C, in the 24-btl. lot, and vitamin B₁₂, in the 12-btl. lot, had been in part omitted or abstracted therefrom; and 403(a)—the label statements (24 btl.) "Each * * * Gelucap Contains:—Vitamin C—30 mg." and (12 btl.) "Each * * * Gelucap Contains:—Vitamin B₁₂—3 mg." were false and misleading.

The libel alleged also that a quantity of Super Rybutol capsules was adulterated and misbranded under the provisions of law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 5876.

DISPOSITION: 1-26-58. Default—destruction.

26741. 7/Eleven Health tablets. (F.D.C. No. 42823. S. No. 36-125 P.)

QUANTITY: 2 metal containers containing about 28,000 tablets at Philadelphia, Pa., in possession of Service Industries.

SHIPPED: 1-15-59, from San Pedro, Calif.

LABEL IN PART: (Metal container) "20,000 Brewers Yeast, Alfalfa & Kelp (Special) Tablets"; (btl. label) "7/Eleven Mineral, Vitamin and Protein Health Tablets Each tablet 8.5 Grain Net Weight * * * Vitamin Components * * * Mgs. Per Tablet Riboflavin 0.0096 Niacin * * * 0.1538 Chloride 1.1100 Carotene * * * 0.0040 Pantothenic Acid * * * 0.0755 Thiamine * * * 0.0232 Pyridoxine * * * 0.0090 Betaine * * * 0.2176 Biotin * * * 0.0002 Inositol 0.9060 Minodione * * * 0.0024 Alpha Tocopherol * * * 0.0532 Xanthophylls * * * 0.0480 Choline * * * 1.1100 * * * Total Vitamin Components * * * 3.7225 Protein (Amino Acids) Components * * * Mgs. Per Tablet Arginine 10.747 Cystine * * * 2.835 Histidine 5.478 Isoleucine 11.884 Lysine 14.914 Leucine 15.200 Methionine 4.686 Phenylalanine 8.732 Threonine 10.280 Tyrosine 9.092 Tryptophane 2.718 Valine 9.328 Glutamic Acid 20.240 Glycine 13.866 * * * Total Protein * * * Components in each 7/Eleven Tablet 140.00 Mineral Components * * * Total Per Tablet Calcium * * * 4.94 Phosphorus * * * 3.58 Iron * * * 0.365 Potassium * * * 7.04 Magnesium * * * 1.93 Manganese * * * 0.94 Iodine * * * 0.37 Sodium * * * 5.80 Chloride * * * 22.12 Sulphur * * * 2.40 * * * Total Mineral Components * * * 49.485 Total U.S.P. Units of all three components for Dietary Supplement=64.175 Directions * * * A Product of Service Industries * * * Philadelphia 34, Pa."

ACCOMPANYING LABELING: Pamphlets entitled "7/Eleven Multiple Mineral, Vitamin and Protein Tablets" and a number of loose bottle labels.

RESULTS OF INVESTIGATION: The tablets in the metal containers were to be packed into bottles labeled as described above. The bottle labels and the pamphlets were prepared and printed by the dealer for use in promoting sales of the tablets.

LIBELED: 2-11-59, E. Dist. Pa.

CHARGE: 403(a)—while held for sale, the labeling of the article, namely, the above-mentioned bottle labels and pamphlets, contained false and misleading representations that the article contained substantially significant amounts of various vitamins, minerals, and proteins; that the total constituents of the article could be measured in terms of units of the U.S. Pharmacopeia; and that the article had nutritional properties which would: prevent and correct all illness and poor health; generate health, pep, energy, virile strength and vigor; prevent deficiency diseases; supply the requirements for basic and essential nutrition; and prevent infection, old age, fatigue and disease; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin, mineral, and protein content, and its label failed to bear, as required by regulations, a statement of the dietary properties upon which such dietary uses were based.

The libel alleged also that the article was misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6067.

DISPOSITION: 1-4-60. Default—destruction.

26742. Vitamins. (F.D.C. No. 44670. S. No. 6-314 R.)

QUANTITY: 24 ctns., each containing 11 boxes, containing 31 individually wrapped tablets, at Providence, R.I.

SHIPPED: 1-18-60, from Boston, Mass., by Boston Pharmacal Co.

LABEL IN PART: (Box top) "One Month's Supply of Vitamins the candy flavored multivitamin * * * Boston Pharmacal Co., A Div. of Brady Associates, Inc., Boston, Mass."

RESULTS OF INVESTIGATION: Examination showed that the article contained less than 50 percent of the declared amount of vitamin B₁₂, and approximately 70 percent of the declared amount of vitamin C.

LIBELED: 6-21-60, Dist. R.I.

CHARGE: 402(b)(1)—while held for sale, the valuable constituents, namely, vitamin B₁₂ and vitamin C, had been in part omitted or abstracted from the article; 403(a)—while held for sale, the label statement "Each tablet contains: * * * B-12 (from cobalamin conc.) 2 meg. C Ascorbic Acid 30 mg." was false and misleading; and when shipped, the name "Vitamins" and the label vignette of confectionery were false and misleading, since such name and vignette suggested and implied that the article was confectionery, whereas, the article was not confectionery, and the label statement "Good Health" was false and misleading since such statement suggested and implied that use of the article would develop good health, whereas, the article would not develop good health; and 403(j)—when shipped, the article purported to be and was represented as a food for special dietary uses by reason of its vitamin and mineral content, and its label failed to bear, as required by regulations, the statement "The need for calcium pantothenate, cobalt, molybdenum, man-